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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,052	11/13/2001	Melvin Levinson	58092-012 (SCVL-110)	2825

7590 06/02/2004
McDermott, Will & Emery
28 State Street
Boston, MA 02109

EXAMINER

ROBERTS, PAUL A

ART UNIT PAPER NUMBER

3731

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/008,052

Applicant(s)

LEVINSON ET AL.

Examiner

Paul A Roberts

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 37-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. -See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/26/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1-40 are pending. Claims 1-36 are elected. Claims 37-40 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell 6234980 in view of Rollband 5310402, in further view of Geary et al. 5269803, in further view of McDevitt et al. 2003/0050589, in further view of De Lucca et al 4,833,238.

Bell discloses the following method:

The first step is to slow the flow of blood to the wound by applying a tourniquet.

The second step is to express blood and/or other bodily fluids from the wound by applying a mechanically generated negative pressure directly to the site.

The third step is to apply an antimicrobial/antiviral agent(s) to the site of the sharps injury, immediately following the expressing step.

The fourth and final step is to apply an adhesive bandage to completely cover the site of the sharps injury.

This method broadly recites most of the limitations steps A) - E). Looking at each step one at a time:

A) Applying a tourniquet to a limb would inherently generate enough force on the limb to at least partially collapse the vessel. Bell doesn't disclose additional information about the structure of the tourniquet. Assuming the Bell tourniquet does not inherently collapse the blood

Art Unit: 3731

vessel, the Geary et al tourniquet would have the necessary structure to affect this end.

Specifically, elements 52 and 54, would press against the vessel to collapse the vessel. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the Geary et al. tourniquet with the Bell method because Bell broadly discloses using a tourniquet in his method and Geary et al. discloses a tourniquet with an improved structure to hasten hemostasis.

B) The bandage inherently applies and maintains force against the closure wound, which would prevent fluid from exiting wound. The use of glucosamines is not disclosed, but the use of antimicrobial agents is disclosed by Bell. There is also no discussion by Bell as to how much force is applied to the wound by the bandage. Rollband teaches a bandage which places pressure on the wound to help slow bleeding and speed hemostasis. The structure of the Rollband bandage is disclosed in column 4, line 10. The structure is not woven but is a fiber. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the Bell bandage with the Rollband bandage since Rollband teaches his bandage is better able to speed hemostasis. McDevitt et al. '589 and De Lucca et al '238 teach chitosan can be used to produce various glucosamines such as poly-N-Acetylglucosamine and Poly-D-glucosamine '589 and '238. Glucosamines are beneficial to place in wounds. McDevitt teaches, " For instance, cationic polymers can help clean wounds because they typically have a strong attraction for negatively charged bacteria and deleterious acidic byproducts. One example of a cationic polymer that is suitable for use in the present invention is chitosan (poly-N-acetylglucosamine, a derivative of chitin) or chitosan salts. Chitosan and its salts are natural biopolymers that can have both hemostatic and bacteriostatic properties. As a result, chitosan can help reduce

Art Unit: 3731

bleeding and infection." Further McDevitt teaches that an acetate salt of the glucosamine may be created and used in the bandage by heating the salt. McDevitt states, "Chitosan salt solutions can be prepared by dissolving a desired concentration of chitosan in an aqueous solution of a desired acid. A chitosan salt solution can be dried by various methods including lyophilization, spray drying or by heating in an oven. The resulting chitosan salt can then be dissolved in water to form a chitosan solution. It is understood that a chitosan salt solution, for example chitosan acetate, does not imply a covalent attachment of chitosan to acetate, but rather comprises a solution containing the acetate salt of chitosan." McDevitt does not disclose the use of poly-D-glucosamine. De Lucca discloses the cationic polymer, poly-D-glucosamine can be made from chitosan. De Lucca states this in col. 2, 35-65. Since poly-D-glucosamine would have the same healing properties as poly-N-acetylglucosamine it can be used interchangeably or in conjunction with poly-N-acetylglucosamine. At the time of the invention it would have been obvious to combine the glucosamines (either as an acetate salt or in solution), poly-D-Glucosamine from De Lucca, and poly-N-acetylglucosamine from McDevitt, with the bandage of Rollband to improve the healing properties of the bandage, because, chitosans "help clean wounds because they typically have a strong attraction for negatively charged bacteria and deleterious acidic byproducts."

C) At this point in the method, the wound has been covered and the needle is already out of the wound. A tourniquet is removed before a bandage according to traditional medical practice and well known first-aid.

D) Once the tourniquet is removed pressure is maintained on the wound by the bandage for a certain period of time.

Art Unit: 3731

E) Eventually, when the wound has healed or a new bandage is required the bandage is removed.

This completes and renders obvious steps A-E of the applicant's invention.

2. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined Bell device as discussed above, and in further view of Lebovic US 6309369. The combined Bell discloses all of claim 1. Bell does not disclose the length of time to maintain the bandage on the wound. Lebovic states a bandage should be continuously applied to a wound for about a day in col. 1, lines 5-25. It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the combined Bell US 3,811,438 to a wound for at least ten minutes because Lebovic teaches that a bandage should be changed once every 24 hours.

Conclusion

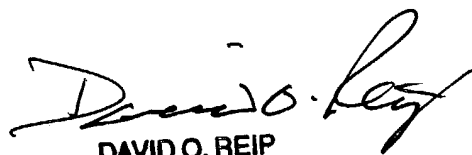
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 703-308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Roberts
Paul.Roberts@uspto.gov
05/18/04


DAVID O. REIP
PRIMARY EXAMINER